

ASSEMBLY BILL

No. 421

Introduced by Assembly Member Dymally

February 14, 2003

An act to add Section 109297 to the Health and Safety Code, relating to cancer.

LEGISLATIVE COUNSEL'S DIGEST

AB 421, as introduced, Dymally. Prostate cancer treatment: PC-SPES.

Existing law prohibits any person from undertaking to treat or alleviate cancer by use of drugs, surgery, or radiation unless the person holds a license issued under a law of this state expressly authorizing the diagnosis and treatment of disease by use of drugs, surgery, or radiation. Existing law requires, upon written request of the State Department of Health Services, any person or entity engaged in treating cancer to furnish to the department a sample, specify the formula, and name all ingredients, of any drug, medicine, compound, or device used or prescribed by the person or entity.

This bill would state declarations and findings with respect to the use of a commercially manufactured product known as PC-SPES by prostate cancer patients.

This bill would require the department to allow the distribution, sale, and use of any product that contains the formula of ingredients contained in PC-SPES if the product is properly labeled in accordance with state and federal law, the product is available for use only by prescription of a physician and surgeon, and the prescribing physician and surgeon makes certain disclosures to the patient.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. (a) The Legislature finds and declares all of the
2 following:

3 (1) A commercially produced product known as PC-SPES has
4 been used by residents in this state diagnosed with prostate cancer.

5 (2) The product is no longer available to residents who desire
6 to continue using the product because the sole producer of the
7 product is prohibited by the State Department of Health Services
8 from distributing or selling the product because the product
9 contains certain drug components and is not labeled and
10 distributed for use as required under state and federal law.

11 (b) It is the intent of the Legislature in enacting this act to
12 establish a procedure under which prostate cancer patients who
13 desire to use a product like PC-SPES may safely and
14 knowledgeably have access to that product.

15 SEC. 2. Section 109297 is added to the Health and Safety
16 Code, to read:

17 109297. (a) Notwithstanding Section 109295, the
18 department shall allow the distribution, sale, and use of any
19 product that contains the formula of ingredients contained in a
20 commercially manufactured product known as “PC-SPES” if all
21 of the following conditions are met:

22 (1) The product is properly labeled in accordance with state and
23 federal law.

24 (2) The product is available for use only by prescription of a
25 physician and surgeon.

26 (3) If the product is being prescribed for a patient with prostate
27 cancer, the physician and surgeon prescribing the product makes
28 all of the following disclosures to the patient and has the patient
29 sign a form acknowledging that these disclosures have been made:

30 (A) A description of any attendant discomforts and risks
31 reasonably to be expected from the use of the product.

32 (B) An explanation of any benefits to the patient reasonably to
33 be expected from the use of the product.



1 (C) A disclosure of any appropriate alternative procedures,
2 drugs, or devices that might be advantageous to the patient, and
3 their relative risks and benefits.

4 (b) In addition to compliance with all other state and federal
5 laws with respect to the labeling, distribution, sale, and use of any
6 product that contains a drug, any product subject to this section
7 shall not be labeled to include any claims for use, except to the
8 extent the product has been approved for that use as required under
9 state and federal law.

